

## Amendment 3

OFFICE OF ACQUISITIONS  
NATIONAL CANCER INSTITUTE

REQUEST FOR PROPOSAL NUMBER: N01CN05014-69

Amendment No.: 3

Date of Issuance: May 31, 2011

The above numbered Request For Proposal (RFP) is amended as set forth below. The hour and date specified for receipt of Offerors remains unchanged.

Offerors MUST acknowledge receipt of the amendment prior to the hour and the date specified in the solicitation or as amended, by separate letter, telegram, or Electronic Mail which includes a reference to the RFP and Amendment number(s). For your convenience, the Proposal Intent Response Form is provided in SECTION J - List of Attachments of this RFP, for this purpose.

FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERORS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER.

This Amendment revises the RFP as stated below:

1. The following Sections of the original RFP are revised in the attachment to this Amendment and are made a part of the RFP:

**Section C, Article C.2.b.1. Reporting Requirements, Other Reports/Deliverables, Information Security and Physical Access Reporting Requirements** on page 10 of the original RFP is revised to include items d-g

**Section F, Article F.2. Deliveries** on page 14 of the original RFP is revised change the numbering for deliverables and to add deliverables 26-29.

**Section H, Article H.20. Information and Physical Access Security** on page 26 of the original RFP is revised to change Item D, on page 29 of original RFP to E. and a new D for HHSAR 352.239-72 is added. Under the new E, item #4 is added.

**Section L.2.b. 6. Information and Physical Access Security** on page 66 of the original RFP is revised to change Item D, on page 70 of original RFP to E. and a new D for HHSAR 352.239-72 is added. Under the new E, item 4 is added.

2. A question was posed regarding the use of Gleason grade tumors in the sample LOIs.

**NCI Response:** In the sample LOIs, NCI/DCP is looking for interventions applicable to precancerous or high risk conditions, but not actual cancer. Thus, the line is drawn at invasion and DCP would not consider a low or intermediate Gleason grade as meeting the definition of precancerous. Any therapies that would be acceptable for the LOIs should focus on premalignant conditions.

3. Several questions have been raised regarding sample LOIs that may have received feedback from DCP through other Program areas.

**NCI Response:** If the Offeror received feedback from NCI/DCP regarding a protocol or general concept for a cancer prevention trial that resulted in changes to the sample LOI that they plan to submit in their proposal (e.g., agent, endpoints, or other aspects of study design), then the Offeror should not use the idea for their sample LOIs. If no feedback was received, then the Offeror may use the idea for their sample LOI.

4. Complexity Model questions were posed related to the following:

How do we determine x, y, z? Do we determine this or does the NCI give us the x, y, and z?

**NCI Response:** The Offeror will determine the amounts for x, y, z. You will note on p. 93 "For purposes of the proposal, the Offeror shall propose base costs for various levels of screening...." In that sentence, in parentheses, is a broad based category for screening 1 and screening 2 at the base cost level. The description of the base cost level for "intervention" is further down in the same paragraph.

Are Offerors to determine the "per subject rate" that is the basic rate, and then multiply it by, say, x2, if we believe that the complexity level is x2 for the study or will NCI give us the "per subject rates"?

**NCI Response:** The Offeror determines the Base level "per subject cost" and then multiplies that Base level by the factors provided. The Base level "per subject cost" needs to reflect the basic cost for the type of study described as the lowest complexity. All other costs flow from the base such that if the study complexity is considered medium or high by the Offeror, then the Offeror would use the "per subject costs" for the factor (x1.5, x2, etc.) that is appropriate for the study when developing the budget.